UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ELICIA CUTSINGER, Plaintiff, v. GYRUS ACMI, INC., GYRUS ACMI, L.P., OLYMPUS CORPORATION OF THE AMERICAS, and OLYMPUS AMERICA INC., Defendants.	Cause No. 4:18-cv-00004 **JURY TRIAL DEMANDED**

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff, Elicia Cutsinger, brings her causes of action against Gyrus Acmi, Inc., Gyrus Acmi, L.P., Olympus Corporation of the Americas, and Olympus America Inc., as follows:

PARTIES

1. Plaintiff, Elicia Cutsinger, is a citizen of Marion County, Missouri.

2. Defendant, Gyrus Acmi, Inc., ("GAI") is a Delaware corporation with its principal place of business in Massachusetts.

3. Gyrus Acmi, L.P., ("GALP") is a Minnesota limited partnership. GAI is the limited partner of GALP. Service may be had by serving their registered agent: CSC-Lawyers Incorporating Services Company, 221 Bolivar St., Jefferson City, MO 65101.

4. Defendant, Olympus Corporation of the Americas ("OCA") is a New York Corporation with its principal place of business in Pennsylvania.

5. Defendant, Olympus America Inc., ("OAI") is a New York Corporation with its principal place of business in Pennsylvania. Service may be had by serving their registered agent: United States Corporation Co., 221 Bolivar St., Jefferson City, MO 65101.

JURISDICTION AND VENUE

6. This is a lawsuit for personal injury damages in excess of $75,000.00. The parties are citizens of different states. This Court has diversity jurisdiction pursuant to 28 U.S.C § 1332.

7. GAI, OCA, and OAI are currently interconnected companies engaged in the business of marketing, distributing, and selling medical devices throughout the United States, including Missouri.

8. On January 11, 2008, GAI submitted a 510(k) application to the United States Food & Drug Administration (FDA) for the GYRUS LPM Plasma Morcellator (hereinafter GYRUS LPM).

9. On or about May 2, 2008, FDA cleared the 510(k) application. This permitted marketing of the device in the United States, including Missouri.

10. As part of the product launch marketing campaign, GAI and GALP established means to train physicians on use of the GYRUS LPM Morcellator nationwide, again including Missouri physicians.

11. As part of the product launch marketing campaign, GAI and GALP developed a direct-to-patient educational campaign which was implemented in Missouri.

12. As part of the product launch marketing campaign, GAI and GALP targeted Missouri physicians.

13. As part of GAI and GALP's general sales effort, and as part of the GYRUS LPM Morcellator marketing effort, GAI and GALP purposely availed themselves to Missouri and contracted with and/or directly employed sales representatives to market their products to Missouri doctors, including Plaintiff's treating physicians and hospitals.

14. Through the use of sales representatives in Missouri, GAI and GALP established channels to communicate with Missouri doctors, hospitals, and to give advice regarding the use of their products including the GYRUS LPM Morcellator, including to Plaintiff's treating physicians.

15. GAI and/or GALP hired Jim O'Day to market GAI products in Missouri.

16. GAI and/or GALP trained Mr. O'Day regarding use of the GYRUS LPM Morcellator with the intent he use his training to market the device in Missouri.

17. GAI and GALP, through the use of sales representatives such as Mr. O'Day, were regularly communicating with Missouri physicians, including Plaintiff's healthcare providers and facilities, and marketing their products in Missouri.

18. Between 2008 and 2010, GAI and GALP marketed to and sold GYRUS LPM Morcellators in Missouri to: Mercy Hospital St. Louis; Doctors Park Surgery Center; Missouri Baptist Medical Center; BJC Health System Procurement; Barnes Jewish St. Peters Hospital; BJC Health Care; Parkland Health Center; Phelps County Reg Med; St. Anthony's Med Ctr-St. Louis; Cox Health Systems South; Cox Health Systems; St John's Health System; St. Joseph Hospital West; Mercy Warehouse St. Louis; Mercy Hospital St. Louis; University of Missouri Healthcare; Jefferson Memorial Hospital; Southeast Missouri Hospital; Cox Health System; SSM St Joseph Hospital West; SSM St Clare Health Center; and Auburn Surgery Center.

19. GAI and GALP, through sales representatives, marketed the GYRUS LPM Morcellator to Danny Schust, MD, and University of Missouri Healthcare.

20. GAI and GALP filled orders for GYRUS LPM Morcellators in the State of Missouri and routinely shipped GYRUS LPM Morcellators into the State of Missouri.

21. GAI and GALP sold GYRUS LPM Morcellators in the State of Missouri including the Gyrus GYRUS LPM Morcellator used on Plaintiff.

22. GAI and GALP entered into contracts in Missouri, conducted business in Missouri, and as set forth below; committed torts in the state of Missouri.

23. GAI and GALP received payments for the sale of GYRUS LPM Morcellators in Missouri.

24. Prior to 2012, all marketing and strategic decisions regarding the GYRUS LPM Morcellator were made by GAI.

25. In 2012, sales functions transitioned to OAI.

26. OAI employed sales representatives in Missouri to continued marketing the GYRUS LPM Morcellator to Missouri doctors and hospitals.

27. OAI sales representatives marketed the GYRUS LPM Morcellator to Plaintiff's surgical physician, Dr. Schust, in Missouri.

28. OAI sales representatives marketed the GYRUS LPM Morcellator to University of Missouri Healthcare.

29. OAI, through sales representatives, established regular channels for giving advice to Missouri doctors.

30. OAI filled sales orders in the State of Missouri.

31. OAI sold GYRUS LPM Morcellators in the State of Missouri including the Gyrus GYRUS LPM Morcellator used on Plaintiff.

32. OAI received payments for the sale of GYRUS LPM Morcellators in Missouri.

33. OAI provided training to Missouri doctors on the use of the GYRUS LPM Morcellator.

34. GAI and OAI are wholly owned subsidiaries of OCA.

35. OCA is responsible for post-marketing surveillance; accounting; legal services; regulatory affairs; and human resources for OAI and GAI.

36. OCA, OAI, and GAI share corporate officers.

37. At all relevant times, OCA controlled the activities of OAI and GAI such that the jurisdictional contacts of OAI and GAI are imputable to OCA.

38. Prior to 2013, OCA made general payments to the University of Missouri Healthcare.

39. Prior to 2013, OCA made general payments to Missouri doctors.

40. Prior to 2013, OCA made general payments to other Missouri hospitals.

41. In 2013, OCA made $26,447.22 in general payments to University of Missouri Healthcare, which includes University of Missouri Women's and Children Hospital, where Plaintiff was morcellated in 2013.

42. In 2015, OCA made $72,228.64 in general payments to University of Missouri Healthcare, which includes University of Missouri Women's and Children Hospital, where Plaintiff was morcellated.

43. In 2016, OCA made $72,292.56 in general payments to University of Missouri Healthcare, which includes University of Missouri Women's and Children Hospital, where Plaintiff was morcellated.

44. This action was originally filed in the Philadelphia Court of Common Pleas.

45. OCA, OAI, and GAI moved for dismissal under the doctrine of forum non-conveniens.

46. OCA, OAI, and GAI represented to the Philadelphia Court "A review of [P]laintiff's claims suggests this matter is properly heard in Missouri;" "a clearly more appropriate forum exists in the State of Missouri (where all served defendants agree to not contest jurisdiction)." The Philadelphia Court granted the motion of OCA, OAI, and GAI.

47. OCA, OAI and GAI have consented to personal jurisdiction in Missouri.

48. Venue is proper in this Court under 28 U.S.C. § 1391 as a substantial part of the events or omissions giving rise to the claim occurred in the Eastern District of Missouri as Plaintiff was diagnosed with leiomyosarcoma in Hannibal, Missouri, and is currently being treated by Dr. Brian Van Tine in St. Louis, Missouri.

49. All conditions precedent to the maintenance of this action have occurred, have been performed, or have been waived.

FACTUAL ALLEGATIONS

50. Plaintiff, ELICIA K. CUTSINGER, underwent a laparoscopic surgical procedure on November 23, 2013 at the Health Care Women's & Children's Hospital in Columbia, Missouri performed by surgeon, Danny Joseph Schust, M.D. The surgery was performed utilizing Defendants' GYRUS LPM to morcellate, or cut into small fragments, Plaintiff's uterus.

51. Plaintiff was subsequently diagnosed with an aggressive type of cancer known as Leiomyosarcoma. The malignant cells were spread throughout her abdomen and pelvis by the GYRUS LPM, thereby upstaging her cancer.

52. The spread of the life-threatening cancer was a direct and proximate result of the use of the GYRUS LPM.

53. There was ample literature collected by and known to the DEFENDANTS (or should have been known to the DEFENDANTS) at or before the time Plaintiff underwent her

laparoscopic procedure which discussed and highlighted the risk of disseminating cancer when using the LPM. DEFENDANTS knew or should have known that their LPM would disseminate and implant occult malignant tissue fragments in the bodies of women undergoing laparoscopic hysterectomies or myomectomies. For example:

a) On August 6, 1991, a patent for a Surgical Tissue Bag and Method for Percutaneously Debulking Tissue was issued that describes the potential for laparoscopic power morcellators to disseminate and implant malignant tissue fragments in the body.

b) The patent for the surgical tissue bag stated: Another problem associated with the debulking, removal or morcellation of large tissue volume is the concern for containing malignant or pathogenic tissue. ***The morbidity of patients significantly increases when malignant cells of such large volume tissue are permitted to come in contact with surrounding healthy tissue***. A malignancy would typically indicate a more invasive procedure in which the cavity is opened and the affected tissue is removed. These invasive open cavity procedures increase the recovery period of the patient and subject the patient to additional discomfort and complications. As a result, the debulking of large malignant tissue volumes percutaneously through an access sheath presents significant morbidity risks to the patient.

c) The patent summary of the invention further stated that, "[C]ontainment of the tissue within the bag also prevents the spread of malignant cells to healthy tissue in the body cavity."

d) The "Surgical Tissue Bag" patent was publically available and was available to the Defendants, and/or known to Defendants, before they first sought approval of their laparoscopic power morcellators

e) Also, prominent medical journals reporting on laparoscopic power morcellators and the risk of spreading undetected cancer also began to accumulate in the 1990s, and continued thereafter.

f) In 1997, Schneider published a case report in a medical journal, known to the Defendants as THE AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY, titled "Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation," which described a patient who underwent a laparoscopic supracervical hysterectomy by manual morcellation. Schneider, Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation, J. AM. OBSTET. GYNECOL., 177(1): 478-9(1997).

g) The following year, the patient died due to the rapid progression of uterine adenocarcinoma that had been undetected prior to surgery. *Id*. at 478.

h) Schneider cautioned that evaluation for malignancy prior to surgery "grows even more important and should be mandatory when uteri are increasingly morcellated by introduction of laparoscopic techniques." *Id.* at 479.

i) In 1998, Hutchins and Reinoehl published a case report in THE JOURNAL OF THE AMERICAN ASSOCIATION OF GYNECOLOGIC LAPAROSCOPISTS, which was or should have been known to the Defendants, in which the authors explained that "[b]ecause of the large quantity of tissue of such a uterus, it would be anticipated that numerous fragments would be generated during morcellation." Hutchins and Reinoehl, Retained Myoma after Laparoscopic Supracervical Hysterectomy with Morcellation, J. AM. ASSOC. GYNECOL. LAPAROSC., 5(3):293-295 (1998).

j) The authors cautioned that the morcellated fragments could become concealed in surrounding organs making it difficult for the surgeon to identify and remove all tissue fragments. *Id*. at 294.

k) In 2005, LaCoursiere et al. published a case report in THE JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY which reported that "[t]he use of a power morcellator may produce smaller fragments than other techniques." LaCoursiere et al., Retained fragments after total laparoscopic hysterectomy, J. MINIM. INVAS. GYNCOL., 12:67-69, 68 (2005).

l) According to the authors, "implantation, rather than resorption of residual fragments of cervix and myometrium can occur," a problem which they reported "ha[d] implications for possible benign and malignant sequelae." *Id*.

m) In 2009, Perri et al published a study and concluded, "In patients with stage I LMS, primary surgery involving tumor injury seems to be associated with a worse prognosis than a total hysterectomy as a primary intervention." Int. J. Gynecol. Cancer 2009; 19:257-260

n) In 2010, in THE JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY, Larraín et al. explained that, "[i]f retained fragments [from morcellation] can establish a blood supply and grow with benign disease, it is of concern that in situations in which an unsuspected malignant lesion is inadvertently morcellated, aberrant fragments will

grow and metastasize." Larraín et al., "Iatrogenic" Parasitic Myomas: Unusual Late Complications of Laparoscopic Morcellation Procedures, MINIM. INVAS. GYNCOL., 17:719-724, 722 (2010) ("Larraín et al. paper").

o) In 2011, Park et al published a study and concluded "Tumor morcellation during surgery increased the rate of abdomino-plevic dissemination and adversely affected DFS and OS in patients with apparently early uterine LMS." Gynecologic Oncology 122 (2011) 255-259

p) In 2012, Seidman et al published a study and concluded "while additional study is warranted, these data suggest uterine morcellation carries a risk of disseminating unexpected malignancy with apparent associated increase in mortality much higher than appreciated currently." PLOS One Nov. 2012, Vol 7, Iss. 11, e50058

q) Based on this evidence *inter alia*, Defendants were on notice that their laparoscopic power morcellators exposed patients to a significant risk of disseminating and worsening occult cancer.

54. DEFENDANTS knew or should have known that for women undergoing laparoscopic hysterectomies or myomectomies for presumed fibroids, the risk of having a hidden deadly sarcoma was much higher than the "1 in 10,000" figure commonly provided to patients. For example:

(a) In 1990, Leibsohn et al. published a study titled "Leiomyosarcoma in a series of hysterectomies performed for presumed uterine leiomyomas" in the AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY in which the authors found that "…women with signs and symptoms of [benign] uterine leiomyomas [fibroids] that warrant hysterectomy have about a 1 in 140 chance of having a uterine leiomyosarcoma." Leibsohn et al., Leiomyosarcoma in a series of hysterectomies performed for presumed uterine leiomyomas, Am. J. Obstet. Gynecol. 162:968-76, 972 (1990) ("Leibsohn et al. paper") (emphasis added).

(b) In 1999, Takamizawa et al. published another study titled "Risk of Complications and Uterine Malignancies in Women Undergoing Hysterectomy for Presumed Benign Leiomyomas" in GYNECOLOGIC AND OBSTETRIC INVESTIGATION, which found that 2/923 women who underwent hysterectomies for presumed benign fibroids had undiagnosable hidden sarcomas before their hysterectomies. Takamizawa et al., Risk of Complications and Uterine Malignancies in Women

Undergoing Hysterectomy for PresumedBenign Leiomyomas, GYNECOL.OBSTET. INVEST., 48:193-196, 196 (1999).

(c) Takamizawa et al. reported that their study results were consistent with the findings of other studies which suggested that 2–5 patients per 1,000 who undergo surgery for presumed fibroids have uterine sarcomas. *Id*.

(d) This evidence was *inter alia* available to Defendants.

(e) However, on information and belief, in seeking approval for their laparoscopic power morcellators decades before Plaintiff's Decedent underwent surgery, and later when promoting their devices to the medical community, Plaintiff and Plaintiff's surgeon, Defendants ignored this data and touted a much lower 1 in 10,000 risk.

55. DEFENDANTS knew or should have known that women could not adequately be screened for malignancy prior to undergoing LPM surgery because certain types of cancers, including sarcomas, can mimic the radiographic appearance of benign uterine fibroids and do not always yield a positive biopsy result upon sampling. For example:

(a) In the 1990, Leibsohn et al. study, discussed *supra*, the authors described the difficulties in diagnosing leiomyosarcoma preoperatively, noting that "abdominal ultrasonography of the pelvis and cervical cytology are not helpful preoperative tests for the diagnosis [of] leiomyosarcoma of the uterus." See Leibsohn et al. paper, at 192.

(b) Additional evidence became available to Defendants in 2001, when Stewart published an article in THE LANCET, which explained that malignant leiomyosarcoma and benign fibroids may share histological features; thereby, making it more difficult for clinicians to identify the malignant potential of smooth muscle uterine tumors. Stewart, Uterine Fibroids, THE LANCET, 357:293-98 (2001).

(c) The difficulty in diagnosing uterine sarcoma preoperatively was not limited to leiomyosarcoma.

(d) In 2008, Bansal et al. published a study in GYNECOLOGIC ONCOLOGY, in which the authors found that the predictive value of endometrial biopsy or curettage for diagnosing uterine sarcoma was very poor and thus "novel diagnostic techniques are needed to accurately identify uterine sarcomas preoperatively." Bansal et al., The utility of

preoperative endometrial sampling for the detection of uterine sarcoma, GNECOL. ONCOL., 110:43-48, 47 (2008).

(e) Similarly, in 2010, Della Badia and Karini published a case report in THE JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY, in which they warned that there was "no reliable method for preoperative diagnosis of endometrial sarcoma" and "[s]ensitivity of preoperative endometrial sampling is only 64% for enabling a diagnosis of this tumor." Della Badia and Karini, Endometrial Stromal Sarcoma Diagnosed after Uterine Morcellation in Laparoscopic Supracervical Hysterectomy, J. MINIM. INVAS. GYNCOL., 17:791-93, 791 (2010).

(f) According to the authors, where malignancy is found before surgery, the standard treatment for uterine sarcoma is a total hysterectomy with staging of the cancer, not tissue morcellation. *Id*.

56. DEFENDANTS knew or should have known that women undergoing surgery with an LPM suffer worse long-term medical outcomes than women undergoing other available treatment options because of the cancer risks associated with the use of these devices. For example:

(a) In 2002, Goto et al. published a study in the INTERNATIONAL JOURNAL OF GYNECOLOGIC CANCER, which reported: "Leiomyosarcoma of the uterus is one of the most difficult neoplasms to cure in gynecologic oncology. Its malignant behaviors such as rapid growth and high rate of metastasis are notorious. The 5-year survival in patients with advanced stages (stage III or higher) is less than 10%, although leiomyosarcoma resembles leiomyoma in clinical features. Until now LMS was diagnosed only in advanced stages or accidentally at total abdominal hysterectomy.[…]Therefore it seems that the effective treatment of LMS is surgical removal of the tumor in the earlier stages. The problem regarding treatment of LMS is the difficult preoperative differential diagnosis of LMS in the early stages from leiomyoma, which is the most common tumor of the uterus." Goto. et al., INT. J. GYNECOL.CANCER, 12:354-361, 358 (2002).

(b) Likewise, in 2003, Morice et al. published an article in the EUROPEAN JOURNAL OF GYNECOLOGIC ONCOLOGY, in which they found a substantial increase in pelvic recurrence of uterine sarcoma at three (3) months in 34 patients with uterine sarcoma who had morcellation during their initial surgery compared with 89 patients without morcellation. Morice et al., Prognostic value of initial surgical procedure for patients

with uterine sarcoma: analysis of 123 patients, EUR. J.GYNAECOL. ONCOL., 24(3-4); 237-40, 238-39 (2003).

(c) In 2008, Einstein et al. presented a prospective study in the INTERNATIONAL JOURNAL OF GYNECOLOGIC CANCER involving all patients who had undergone any type of hysterectomy for presumed benign disease and were, subsequently, referred to Memorial Sloan-Kettering between January 2000 and March 2006 with diagnosed malignancy based on the final surgical pathology. Einstein et al., Management of uterine malignancy found incidentally after supracervical hysterectomy or uterine morcellation for presumed benign disease, INT. J.GYNECOL. CANCER, 18: 1065-70, 1066 (2008).

(d) According to their review, an astounding 40% percent of patients who underwent morcellation were found to have upstaged cancer compared with only 8% who had a supracervical hysterectomy. *Id*. at 1069.

(e) According to the authors, "[this] data support this trend toward worse outcomes in patients who had morcellation procedures." *Id.*

(f) In 2009, Perri et al. published an article in the INTERNATIONAL JOURNAL OF GYNECOLOGICAL CANCER, in which they explained: [u]nfortunately, however, it is not unusual to diagnose LMS [leiomyosarcoma] only postoperatively because its symptoms and signs resemble those of benign leiomyomas (LMs), and there are no imaging techniques for differentiation between the two. Consequently, on the assumption that they have LM, some patients with LMS are treated initially with hysteroscopic or abdominal myomectomy, subtotal hysterectomy, or laparoscopic hysterectomy or myomectomy with a morcellator knife. Those surgical techniques, unlike total abdominal hysterectomy (TAH), are likely to involve tumor injury or cut-through. Perri et al., Uterine Leiomyosarcoma: Does the Primary Surgical Procedure Matter?, INT. J. GYNECOL. CANCER, 19(2): 257- 260, 257 (2009).

(g) According to the authors, "[their] data demonstrate[d] a significant disadvantage for patients in whom the primary surgery had involved tumor cut-through." *Id*. at 260.

(h) In the 2010 Larraín et al. study, discussed *supra*, they commented that "[i]f malignancy is suspected or known preoperatively, morcellation is formally proscribed. However, this situation [spread of malignant tissue] may occur, even if an appropriate preoperative workup including cervical cytologic analysis and endometrial sample are routinely performed." Larraín et al. paper at 722-23.

57. DEFENDANTS knew or should have known that when malignant tissue undergoes Laparoscopic Power Morcellation, the resultant tissue specimens can delay diagnosis because the tissue's ground up condition can prevent the pathologist from properly identifying and staging cancer, which can further worsen a patient's prognosis and treatment outcomes. For example:

(a) In 2005, Rekha et al. discuss in their paper published in the AUSTRALIAN AND NEW ZEALAND JOURNAL OF OBSTETRICS AND GYNAECOLOGY, "[o]ne of the disadvantages of tissue morcellation is loss of the gross appearance of the specimen and the possibility of missing the most suspicious area for the microscopic evaluation." Rekha et al., Unexpected complications of uterine myoma morcellation, Aust. N.Z. J. Obstet. Gynecol., 45: 248- 49, 248 (2005).

(b) Rekha et al.'s case report involved a 40-year-old woman who underwent total laparoscopic hysterectomy for presumed benign uterine fibroids died several months after her initial surgery from dissemination of occult leiomyosarcoma. *Id.*

(c) According to the authors, the patient's "malignant component was missed at the time of initial histological evaluation due to evaluation of limited tissue." *Id.*

(d) Published in 2011, Hagemann et al. also discuss the difficulty of analyzing morcellated specimens in their case series "Risk of Occult Malignancy in Morcellated Hysterectomy: A Case Series" that appeared in the INTERNATIONAL JOURNAL OF GYNECOLOGICAL PATHOLOGY. Hagemann et al., Risk of Occult Malignancy in Morcellated Hysterectomy: A Case Series, INT. J. GYNECOL.CANCER, 30:478-83 (2011).

(e) In their article, Hagemann et al. explained that "[t]hese [morcellated] specimens are examined in the surgical pathology laboratory where, by their fragmented and unoriented nature, they present a special challenge to the pathologist. There is little evidence to guide the pathologic examination of these specimens." *Id.* at 481-82.

58. Indeed, morcellated specimens are poorly amenable to pathologic examination, because the morcellation abolishes many of the anatomic features that allow for meaningful gross description, including the notions of orientation, dimension, adjacency, border, and margin.

59. As set forth herein, there were numerous journal articles and published studies available to the DEFENDANTS examining an LPMs' potential to spread and worsen a woman's occult cancer. This evidence should have placed DEFENDANTS on notice that their LPMs were associated with and/or would cause the dissemination and upstaging of a woman's occult cancer.

60. On April 17, 2014, the FDA issued a safety communication discouraging the use of laparoscopic power morcellation during hysterectomy or myomectomy surgical procedures for uterine fibroids. The FDA announced, "If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival." The FDA discouraged this practice because of this risk and the fact that "there is no reliable method for predicting whether a women with fibroids may have a uterine sarcoma."

61. Based on the FDA safety communication released in 2014, another manufacturer, Johnson & Johnson, suspended worldwide sales of their LPMs and later removed these devices altogether. Their reasoning was sound, if not overdue: "The risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain." The FDA further warned that based on an "FDA analysis of currently available data, it is estimated that **1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma**." *Id.* (emphasis added).

62. Significantly, in its "Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids," the FDA listed the studies upon which it relied in reaching its conclusions on the prevalence of unsuspected uterine sarcoma and uterine leiomyosarcoma.

63. The studies cited by the FDA were published in prominent medical journals, ranging in publication date from 1980 to 2014. Significantly, the majority of the studies cited by the FDA were available to DEFENDANTS **prior to the date on which Plaintiff ELICIA K. CUTSINGER underwent her surgery**.

64. In 2014, FDA identified the following studies as relevant to the prevalence of uterine sarcoma in the setting of presumed benign fibroid. All studies identified by FDA predate Mrs. Cutsinger's procedure:

Table 2. Studies reporting unsuspected uterine sarcomas and LMS, 1980-March, 2014+ (Rates are per 1,000 patients)

Author	Year Published	Study Years	Procedure(s)	Total Patients	Number of Uterine Sarcomas	Rate of Uterine Sarcoma (95%CI)	Number LMS	Rate of LMS (95% CI)
Leibsohn[33]	1990	1983-1988	Hysterectomy	1429	7	4.90 (1.97-10.07)	7	4.90 (1.97-10.07)
Reiter[36]	1992	1986-1989	Hysterectomy	104	0	0.00 (0.00-34.85)	0	0.00 (0.00-34.85)
Parker[37]	1994	1988-1992	Hysterectomy or Myomectomy	1332	3	2.25 (0.47-6.57)	1	0.75 (0.02-4.18)
Takamizawa[38]	1999	1983-1997	Hysterectomy	923	2	2.17 (0.26-7.81)	1	1.08 (0.03-6.02)
Sinha[39]	2008	1998-2005	Myomectomy	505	2	3.96 (0.48-14.23)	2	3.96 (0.48-14.23)
Kamikabeya[40]	2010	1987-2008	Hysterectomy	1364	2	1.47 (0.18-5.29)	1	0.73 (0.02-4.08)
Rowland[41]	2011	2006-2011	Hysterectomy	1115	5	4.48 (1.46-10.43)	3	2.69 (0.56-7.84)
Leung[42]	2012	1999-2005	Hysterectomy	1297	3	2.31 (0.48-6.75)	3	2.31 (0.48-6.75)
Seidman[43]	2012	2005-2010	Myomectomy	1091	2	1.83 (0.22-6.61)	1	0.92 (0.02-5.10)

65. In 2014, FDA identified the following studies as relevant to the outcomes of morcellated uterine sarcoma. All but two (2) studies predate Mrs. Cutsinger's procedure:

Table 4. Outcomes after morcellation of an unsuspected tumor, 1980-March, 2014

Author	Year Published	Study Years	Study Design	Total Number Patients	Procedure	Cancer/Neoplasms	Outcome(s)
Monice[40]	2003	1977-1997	Retrospective cohort study	123	Morcellation versus no morcellation	Leiomyosarcoma, Endometrial stromal sarcoma Carcinosarcoma	Recurrence Disease-Free Survival Overall Survival
Park[42]	2011	1989-2010	Retrospective cohort study	56	Morcellation versus total abdominal hysterectomy	Leiomyosarcoma	Recurrence Disease-Free Survival Overall Survival
Park[41]	2011	1989-2010	Retrospective cohort study	50	Morcellation versus total abdominal hysterectomy	Endometrial stromal sarcoma	Recurrence Disease-Free Survival Overall Survival
Seidman[43]	2012	2005-2010	Descriptive chart review	14	Morcellation only	Leiomyosarcoma, Endometrial stromal sarcoma STUMP+ Cellular leiomyoma Atypical leiomyoma	Mortality
Oduyebo[44]	2014	2005-2012	Descriptive chart review	21	Morcellation only	Leiomyosarcoma STUMP+	Recurrence Mortality
George[45]	2014	2007-2012	Retrospective cohort study	58	Morcellation versus total abdominal hysterectomy	Leiomyosarcoma	Recurrence Disease-Free Survival Overall Survival

*One patient also had ovarian cancer
+ Smooth muscle Tumor of Uncertain Malignant Potential

66. In 2013, the findings in the published medical literature on the prevalence of uterine sarcoma in the setting of presumed benign fibroid, and the outcomes of morcellated sarcoma, constituted a safety signal.

67. On July 10 and 11 of 2014, the FDA convened an Advisory Committee meeting of the Obstetrics and Gynecological Medical Device Advisory Committee on LPMs to discuss, among other topics, "whether a 'boxed warning' related to the risk of cancer spread should be required for Laparoscopic Power Morcellators."

68. On November 24, 2014, the FDA updated its prior safety communication regarding power morcellators. Rather than merely discouraging power morcellation in the treatment of uterine fibroids, the FDA warned against "the use of Laparoscopic Power Morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids."

69. In its warning, the FDA stated, "[I]f laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will

spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's long-term survival." According to the Safety Communication, the FDA, in an unprecedented action, issued, an Immediately In Effect ("IIE") guidance that asked manufacturers of LPMs to include two contraindications and a boxed warning in its product labeling. Said warning advised the medical community against using LPMs in the majority of women undergoing myomectomy or hysterectomy, and recommended that doctors share this information with their patients.

70. A boxed warning is the strongest warning the FDA implements for medical devices. Upon information and belief, this is the first time the FDA has used its IIE authority to warn the public about a product.

71. Recognizing that LPMs pose a heightened risk of spreading cancerous tissue within the abdomen and pelvis, the FDA recommended that manufacturers of LPMs prominently include the following contraindications and boxed warning in their product labeling:

> ***CONTRAINDICATION: Laparoscopic Power Morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.***
> ***CONTRAINDICATION: Laparoscopic Power Morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:***
> - ***Peri- or post-menopausal, or***
> - ***Candidates for en bloc tissue removal, For example:through the vagina or via a mini-laparotomy incision.***
>
> ***WARNING:*** **Uterine tissue may contain unsuspected cancer. The use of Laparoscopic Power Morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.**

72. The information forming the basis of the 2014 label change was known, or knowable in 2013, because the majority of the literature reviewed by FDA pre-dated Mrs. Cutsinger's procedure.

73. The state of scientific knowledge in 2013 regarding the use of power morcellation in the setting of presumed benign fibroid warranted contraindicating the device in peri/post menopausal women; or candidates for enbloc removal.

74. The state of scientific knowledge in 2013 regarding the use of power morcellation in the setting of presumed benign fibroid warranted a warning that power morcellation during fibroid surgery may spread cancer and decrease the long term survival of patients.

75. The state of scientific knowledge in 2013, and before, regarding the use of power morcellation in the setting of presumed benign fibroid warranted the development of tissue containment systems through CAPA, or other applicable safety protocols, to mitigate the risk of tissue spread.

76. LPMs are not necessary for the treatment of uterine fibroids. Safer, more reasonable and feasible alternative methods that do not employ the use of an LPM have existed for decades for treating uterine fibroids. For example, other surgical methods have long been widely used, and are still used, for the safe removal of the uterus and uterine fibroids including, but not limited to, vaginal hysterectomies and abdominal hysterectomies whereby the uterus can be removed intact rather than being fragmented by an LPM in such a way that cancer cells are disseminated, seeded and spread throughout the abdomen.

77. Further, minimally invasive techniques were available in 2013 that avoid power morcellation that could be utilized to safely perform a hysterectomy. Such techniques include, but are not limited to, mini laparotomy, LAVH, and TLH.

78. DEFENDANTS marketed and over promoted the GYRUS LPM as a safer morcellator than competitor morcellators. Specifically, DEFENDANTS represented to the surgical community the cutting mechanism of GYRUS LPM reduced the risk of tissue seeding.

79. This representation was baseless as, in 2014, ACOG provided "There are some power morcellators that rely on electrical current rather than a rotating blade to shave tissue, and there are no studies on whether this mitigates the possibility of tissue dissemination."

The Use Of The GYRUS LPM In ELICIA K. CUTSINGER's Surgery

80. At the time of her hysterectomy procedure Ms. Cutsinger was 53 years old, peri-post menopausal and a candidate for en bloc removal.

81. The presumably benign fibroid tissue removed by ELICIA K. CUTSINGER's physician was in fact an incurable and aggressive form of cancer known as leiomyosarcoma. In cutting, shredding and fragmenting the uterus while still within ELICIA K. CUTSINGER, the LPM disseminated and seeded the cancer throughout her pelvis and abdominal cavity thereby worsening her long-term prognosis and the natural course of her cancer.

82. ELICIA K. CUTSINGER has undergone chemotherapy and surgical treatment in an attempt to slow the progression of her disease. ELICIA K. CUTSINGER continues to undergo serial imaging studies and palliative chemotherapy in an attempt to monitor the progression of her disease and preserve quality of life. Leiomyosarcoma is highly aggressive and incurable.

DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

83. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

84. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injuries, and the tortious nature of the wrongdoing that caused the injuries.

85. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with ELICIA K. CUTSINGER's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the GYRUS LPM was not discovered, and through reasonable care and due diligence could not have been discovered, until a date shortly prior to the filing of Plaintiffs' claims. Therefore, under the appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

86. The running of the statute of limitations in this cause is tolled due to equitable tolling. DEFENDANTS are estopped from asserting a statute of limitations defense due to DEFENDANTS' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and ELICIA K. CUTSINGER's physicians who were unaware of the true risks associated with the use of the GYRUS LPM. As a result of DEFENDANTS' fraudulent concealment, Plaintiff was unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the DEFENDANTS.

87. DEFENDANTS are estopped from asserting a statute of limitations defense because all DEFENDANTS fraudulently concealed from Plaintiff and her physicians the nature of their injuries and the connection between the injuries and DEFENDANTS' tortious conduct.

COUNT ONE
STRICT PRODUCT LIABILITY – FAILURE TO WARN AND INSTRUCT AGAINST ALL DEFENDANTS

88. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

89. DEFENDANTS are distributors, marketers, and sellers of the GYRUS LPM.

90. DEFENDANTS placed GYRUS LPM's into the stream of commerce in the course of their business.

91. DEFENDANTS transferred and sold the GRYUS LPM used on Plaintiff, and others, in the course of their business.

92. The GYRUS LPM reached end users in Missouri in sealed containers and in the same condition as when sold.

93. The GYRUS LPM was unreasonably dangerous at the time of sale when used as reasonably anticipated.

94. Plaintiff's healthcare providers did not alter the GRYUS LPM.

95. Plaintiff's healthcare providers used the GRYUS LPM for its intended use and in a manner reasonably anticipated.

96. The GRYUS LPM did not function as intended and malfunctioned as the GRYUS LPM disseminated malignant tissue throughout Plaintiff's peritoneum and resulted in spread of her leiomyosarcoma.

97. The GYRUS LPM failed to perform in the manner reasonably to be expected in light of its nature and intended function as the device disseminated malignant tissue throughout her peritoneum and resulted in spread of her leiomyosarcoma

98. MO Rev. Stat. § 537.762 is not applicable as the drafter of the Instructions for Use is a foreign entity and not subject to personal jurisdiction in Missouri.

99. The Instructions for Use for the GYRUS LPM, which accompanied the product, and was distributed by DEFENDANTS, and used in connection with their marketing efforts provided:

The use of the GyrusACMI Workstation is contraindicated when, in the

judgment of the physician, bipolar electrosurgical procedures would contrary to the best interests of the patient.

100. The GYRUS LPM Instruction for Use were inadequate and defective in the following particulars:

a) Failing to contraindicate the device in peri/post-menopausal women;

b) Failing to contraindicate the device in women who were candidates for en bloc removal;

c) Failing to disclose the limitations of pre-operative diagnosis of uterine sarcoma;

d) Failing to disclose a prevalence rate of uterine leiomyosarcoma of 1/500 in the setting of presumed benign fibroid;

e) Failing to disclose that morcellation of unsuspected malignancy worsens prognosis.

101. The above inadequacies rendered the GYRUS LPM unreasonably dangerous and defective when put to its anticipated use as a surgical tool during hysterectomy procedure.

102. Plaintiff's healthcare providers relied on the Instruction for Use disseminated by Defendants.

103. Plaintiff's healthcare providers were without knowledge of the dangerous characteristics of the GYRUS LPM.

104. Had Plaintiff's healthcare providers been given adequate warnings and instructions, they would not have utilized the GYRUS LPM during her procedure as the device would be contraindicated for use with Plaintiff due to her age.

105. As a direct and proximate result of the inadequate and defective warnings disseminated by DEFENDANTS as set forth above, ELICIA K. CUTSINGER was treated with the GYRUS LPM, and as a result Plaintiff suffered, and continue to suffer, the injuries and damages as set forth herein.

COUNT TWO
STRICT PRODUCT LIABILITY – DESIGN DEFECT
AGAINST ALL DEFENDANTS

106. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

107. DEFENDANTS are distributors, marketers, and sellers of the GYRUS LPM.

108. DEFENDANTS placed to GYRUS LPM into the stream of commerce in the course of their business.

109. The GYRUS LPM reached end users in Missouri in sealed containers and in the same condition as when sold.

110. DEFENDANTS transferred and sold the GRYUS LPM used on Plaintiff, and others, in the course of their business.

111. MO Rev. Stat. § 537.762 is not applicable as the designer and manufacturer of the GYRUS LPM is a foreign entity and not subject to personal jurisdiction in Missouri.

112. The GYRUS LPM sold and distributed by DEFENDANTS was defective in design at the time of sale and unreasonably dangerous in the following ways, but not limited to:

a) Defective in design because it can upstage, disseminate and seed malignant and nonmalignant cells and tissue;

b) Defective in design and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of the GYRUS

LPM;

c) Defective in design, making use of the GYRUS LPM more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's underlying condition;

d) Defective in design, making use of the GYRUS LPM more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

e) Defective in design in that the GYRUS LPM utilized electrocautery which precluded use of the device in conjunction with a tissue containment system;

f) Defective in design in that the GYRUS LPM utilized electrocautery which created smoke in the surgical space which interferes with visibility.

113. ELICIA K. CUTSINGER, was injured as result of the above described defects in that the GYRUS LPM spread malignant tissue throughout her pelvis and abdomen.

114. The above described defects rendered the product unreasonably dangerous for its intended use.

115. Plaintiff's healthcare providers did not alter the GYRUS LPM and used the GYRUS LPM for its intended use and in a reasonably anticipated use.

116. ELICIA CUTSINGER was morcellated by the GYRUS LPM in an open setting and without the use of a tissue containment system.

117. A tissue containment system is a safety feature which reduces the risk of peritoneal spread of malignant cells during power morcellation.

118. A tissue containment system is a plastic barrier which, when insufflated, conforms to the contours of the patients abdomen. Morcellation is performed within the containment bag and the entire bag, including the specimen removed.

119. DEFENDANTS currently market the Pneumoliner Tissue Containment System in conjunction with the PK Morcellator.

120. DEFENDANTS market the Pneumoliner as "provid[ing] a barrier between target tissue and non-targeted abdominal contents" and "maintain[s] a barrier to the escape of fluids, cells and tissue fragments."

121. There was no scientific, engineering, or technical barrier to creating a Tissue Containment System for use in connection with the GYRUS LPM in November 2013.

122. The GYRUS LPM was capable of being made safer in 2013 through use of Tissue Containment System to mitigate the risk of tissue spread.

123. The absence of a tissue containment system rendered the GYRUS LPM defective and unreasonably dangerous in design.

124. Had ELICIA K. CUTSINGER's, procedure utilized a tissue containment system and morcellation been performed in a closed environment, malignant tissue and cells would not have been disbursed throughout her abdomen and pelvis.

125. ELICIA K. CUTSINGER, through her treating physicians, used the GYRUS LPM for its intended purpose and could not have discovered any defect therein through the exercise of due care.

126. As a direct and proximate result of the defects in the design of the GYRUS LPM sold and distributed by of DEFENDANTS as set forth above, ELICIA K. CUTSINGER was

treated with the GYRUS LPM, and as a result, Plaintiff suffered and continue to suffer injuries and damages as set forth herein.

COUNT THREE
NEGLIGENT MISREPRESENTATION and FRAUD AGAINST OAI and GAI/GALP

127. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

128. As part of the marketing effort regarding the GYRUS LPM, OAI and GAI/GALP created programs to train physicians on the use of the GYRUS LPM.

129. As part of the marketing effort regarding the GYRUS LPM, OAI and GAI/GALP utilized sales representatives to market the device to doctors.

130. At all relevant times, OAI and GAI/GALP had control over the materials used by sales representatives, and representations made at OAI/GAI sponsored physician training.

131. At all relevant times, OAI and GAI/GALP had control over the content of marketing materials.

132. OAI and GAI/GALP trained physicians, including Plaintiff's healthcare providers, that the GYRUS LPM "reduced the chance of sequelae seeding."

133. OAI and GAI/GALP marketed the GYRUS LPM to Plaintiff's healthcare providers as having a "reduced the chance of sequelae seeding."

134. In comparing the GYRUS LPM to competitor power morcellators, OAI and GAI/GALP represented that bladed morcellators "can lead to sequelae seeding by spinning tissue."

135. These representations were based on comments by Dr. Thomas Lyons.

136. These representations were material as they relate to the safety of the device.

137. During bench testing on the GYRUS LPM, Dr. Lyons commented that the SORD device had a lowered risk of seeding cancerous and pre-cancerous cells compared to competitor products since "RF cutting effectively destroys cells, and that without rotating parts, unlike mechanical morcellators the SORD does not cast tissue."

138. Dr. Lyons is paid consultant of Defendants and has received hundreds of thousands of dollars in payments from Defendants.

139. OAI and GAI/GALP adopted the statements of Dr. Lyons and utilized them to market the GYRUS LPM as a safer alternative to bladed morcellators in education brochures disseminated by sales representatives and/or used in connection with physician training.

140. Specifically, the "Introduction, Tips, and Techniques" brochure contains the false representations mentioned above and was a document used by Sales Representatives to market the device.

141. These representations were false and misleading and not based on valid science.

142. These representations were negligently made and were done with the intent healthcare providers, including Mrs. Cutsinger's healthcare providers, rely on it.

143. Further, this representation was intentionally made with knowledge of its falsity and/or ignorance of its truth, and with the intent that healthcare providers, including Mrs. Cutsinger's healthcare providers, rely upon it.

144. These representations were made in the course of the business of OAI, GAI/GALP.

145. OAI, GAI/GALP made this false representation with a profit seeking motive and with the intent to generate sales of their product by falsely claiming it was safer than the competition.

146. This representation was made, by sales representatives, including, but not limited to, Mr. O'Day, and/or at physician training events, to Plaintiff's healthcare providers prior to the date of Mrs. Cutsinger's procedure.

147. Plaintiff's healthcare providers relied on this representation in the selecting the GYRUS LPM for Plaintiff's procedure.

148. Plaintiff's healthcare providers had a right to rely on the truthfulness of representations made by OCA/GAI/GALP concerning the safety of the GYRUS LPM.

149. Plaintiff's healthcare providers were ignorant of the falsity of the representation that the GYRUS LPM reduced the risk of seeding.

150. In 2014, ACOG provided "There are some power morcellators that rely on electrical current rather than a rotating blade to shave tissue, and there are no studies on whether this mitigates the possibility of tissue dissemination."

151. Had Plaintiff, or her healthcare providers, known there were no studies verifying the representations made by Defendant, they would not have used the device during her hysterectomy, or relied on the statements as true.

152. This negligent/intentional misrepresentation regarding GYRUS LPM was a direct and proximate cause of Plaintiffs' injuries. As a direct and proximate result of the representations of DEFENDANTS as set forth above, Plaintiff suffered, and will continue to suffer into the future, injuries and damages, as set forth herein.

COUNT FOUR
NEGLIGENT UNDERTAKING AND TRAINING AGAINST OAI and GAI/GALP

153. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

154. OAI and GAI/GALP are liable to Plaintiff under state common law and/or Restatement (Second) of Torts § 324A (1965) due to their negligent training, advising and instructing of the physicians who use the GYRUS LPM in their surgical procedures.

155. The OAI and GAI/GALP trained, advised, and instructed physicians in using the GYRUS LPM in their surgical procedures. The training, advising and instructing of the physicians was done because it was necessary for the protection of patients such as ELICIA K. CUTSINGER.

156. However, OAI and GAI/GALP failed to exercise reasonable care in training, advising, and instructing these physicians because OAI and GAI/GALP never undertook to train these physicians on the risks and dangers associated with upstaging, disseminating and seeding of malignant cells by the GYRUS LPM. Their failure to undertake these matters with reasonable care increased the risk of harm to patients such as ELICIA K. CUTSINGER.

157. Specifically, OAI and GAI/GALP negligence includes but is not limited to the following:

a) Failing to train medical community, physicians, ELICIA K. CUTSINGER and her physicians with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with the use of the GYRUS LPM, including the risk that the GYRUS LPM can upstage, disseminate and seed malignant cells; and/or that there existed safer and more or equally effective alternative products;

b) Failing to train the medical community, physicians, ELICIA K. CUTSINGER and her physicians on the known, or knowable, prevalence of LMS in the setting of presumed benign fibroid;

c) Failing to train the medical community, physicians, ELICIA K. CUTSINGER and her physicians on the limitations of pre-operative testing to detect a uterine sarcoma;

d) Failing to train the medical community, physicians, ELICIA K. CUTSINGER and her physicians on the increasing risk of leiomyosarcoma with increased age and menopausal status; and

e) Failing to train the medical community, physicians, ELICIA K. CUTSINGER and her physicians on proper patient selection;

158. As a direct and proximate result of the negligent acts and/or omissions of the OAI and GAI, Plaintiff suffered injuries and damages, as set forth herein.

COUNT FIVE
NEGLIGENT FAILURE TO WARN AGAINST ALL DEFENDANTS

159. Defendants are liable under Restatement (Second) of Torts § 388.

160. At all relevant times, OCA was responsible for post-marketing safety surveillance regarding the GYRUS LPM.

161. At all relevant times, OAI and GAI/GALP employed sales representatives to market the GYRUS LPM to Plaintiff's healthcare providers.

162. At all relevant times, Defendants owed a duty of reasonable care to provide healthcare providers with adequate warnings regarding the use of the GYRUS LPM.

163. By 2013, there existed sufficient published data regarding the prevalence of LMS, and outcomes of morcellated LMS, to constitute a safety signal.

164. Defendants knew, or had reason to know, the GYRUS LPM was likely to be dangerous for its intended use.

165. Defendants had no reason to believe that Plaintiff's healthcare providers would realize the dangers posed by intended use of the GYRUS LPM.

166. In light of the safety signal which existed by 2013, Defendants negligently failed to provide doctors and hospitals with adequate warnings.

167. As a direct and proximate result of this failure, Plaintiff's healthcare providers selected the GYRUS LPM for her procedure which resulted in the injuries set forth herein.

DAMAGES

168. Plaintiff would show that as a proximate result of defects in the product and negligence of Defendants, Plaintiff has suffered serious and disabling injuries of a permanent nature, including the following:

(a) Loss of earnings, household services, and fringe benefits in the past. Likewise, the disability from which she now suffers and will, in all reasonable medical probability, continue to suffer for the rest of her life, has caused her earning capacity and ability to perform household services to be permanently and materially diminished in the future;

(b) Plaintiff has suffered great physical pain and mental anguish in the past, and in all reasonable medical probability, will continue to suffer, on a permanent basis, great physical pain and mental anguish in the future;

(c) As a result of the injuries which Plaintiff sustained, she has been afflicted with a substantial degree of physical impairment which, in all reasonable medical probability, is permanent;

(d) Plaintiff has suffered loss of enjoyment of life as a result of the injuries incurred and will continue to suffer loss of enjoyment of life in the future;

(e) Plaintiff has suffered disfigurement as a result of the injuries incurred and will continue to suffer disfigurement in the future; and

(f) Plaintiff has also been forced to incur expenses for medical and hospital care as a direct result of the injuries complained of herein, and in all reasonable medical probability, as a result of the injuries complained of herein, she will continue to incur medical and hospital expenses for the remainder of her lifetime.

JURY DEMAND

169. Plaintiff demands that all issues of fact in this case be tried to a properly empaneled jury.

CONCLUSION AND PRAYER

WHEREFORE, Plaintiff requests trial by jury and that the Court grants her the following relief against the DEFENDANTS, on all counts of this Complaint, including:

(a) Money Damages representing fair, just, and reasonable compensation for their respective common law and statutory claims in excess of $75,000.00;

(b) Punitive and/or Treble Damages pursuant to state law;

(c) Attorneys' fees pursuant to state law;

(d) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;

(e) Costs of suit and expenses;

(f) Delay Damages; and

(g) Such other relief as is deemed just and appropriate.

Respectfully submitted,

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